

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Cynthia B. ROBINSON, et al.

Serial Number: 10/698,079

Filing Date: October 29, 2003

Title: COMBINATION OF
DEHYDROEPIANDROSTERONE OR
DEHYDROEPIANDROSTERONE-
SULFATE WITH AN
ANTICHOLINERGIC
BRONCHODILATOR FOR TREATMENT
OF ASTHMA OR CHRONIC
OBSTRUCTIVE PULMONARY DISEASE

Group Art Unit: 1617

Examiner: Kevin J. Capps

CONFIRMATION NO: 9159

FILED ELECTRONICALLY ON: February 2, 2007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- A. ☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;
-- OR --
 - ☒ (3) It is being filed before the mailing of a first Office action on the merits;
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(e) provided concurrently herewith;
-- OR --
 - ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);
-- AND --
 - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ 37 CFR §1.97(e). Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);
-- AND/OR --
 - ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);
-- AND/OR --
 - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E. ☒ Statement Under 37 C.F.R. §1.704(d). Item Nos. 1 and 13 of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant

to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2), **except Item Nos. 14 thru 28 which are not believed to be relevant to the instant claims. However, Applicants will provide copies of Item Nos. 14 thru 28 if requested.**

-- AND/OR --

☒ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 30775-716.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: February 1, 2007

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(650) 493-9300
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By: Albert P. Halluin
Albert P. Halluin, Reg. No. 25,227

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|--|---|----|---|--------------------------|---------------------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/698,079 |
| | | | | Filing Date | October 29, 2003 |
| | | | | First Named Inventor | Cynthia B. Robinson |
| | | | | Art Unit | 1617 |
| | | | | Examiner Name | Kevin J. Capps |
| Sheet | 1 | Of | 3 | Attorney Docket Number | 30775-716.201 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | 1. | US 2002/0032160 | 03/14/2002 | Nyce | |
| | 2. | US 2004/0067920 | 04/08/2004 | Leonard et al. | |
| | 3. | US 2004/0082522 | 04/29/2004 | Nyce | |
| | 4. | US 2005/0101545 | 05/12/2005 | Robinson et al. | |
| | 5. | US 4,501,729 | 02/26/1985 | Boucher et al. | |
| | 6. | US 4,956,355 | 09/11/1990 | Prendergast | |
| | 7. | US 6,635,629 | 10/21/2003 | Raymond et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | 8. | EP 429187 B1 | 01/05/1994 | Bourke et al. | | |
| | 9. | EP 934745 B1 | 04/28/2004 | Kennedy | | |
| | 10. | GB 2240472 A | 08/07/1991 | Masterson | | |
| | 11. | WO 1991/04030 | 04/04/1991 | Daynes et al. | | |
| | 12. | WO 1996/25935 | 08/29/1996 | Nyce | | |

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| Examiner Signature | Date Considered |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Docket No. 30775-716.201

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| Sheet | 2 | Of | 3 | Attorney Docket Number | 30775-716.201 |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|----------------|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ | |
| | 13. | CRETICOS, P. S. Managing asthma in adults. Am J Manag Care. 2000; 6(17 Suppl):S940-63. | | |
| | 14. | ABOU-GHARBIA, et al. Synthesis of dehydroepiandrosterone sulfate and 16 alpha-halogenated steroids. J Pharm Sci. 1981; 70(10):1154-7. | | |
| | 15. | CLARK, et al. The effects of various methods of sacrifice and of ethanol on adenosine levels in selected areas of rat brain. J Neurosci Methods. 1988; 25(3):243-9. | | |
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| | 21. | MILEWICH, et al. Androstenedione metabolism in human lung fibroblasts. J Steroid Biochem. 1986; 24(4):893-7. | | |
| | 22. | MILEWICH, et al. Metabolism of androsterone and 5 alpha-androstane-3 alpha,17 beta-diol in human lung tissue and in pulmonary endothelial cells in culture. J Clin Endocrinol Metab. 1985; 60(2):244-50. | | |

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| Examiner Signature | Date Considered |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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| | 23. | MILEWICH, et al. Metabolism of dehydroisoandrosterone and androstenedione by the human lung in vitro. J Steroid Biochem. 1977; 8(4):277-84. | |
| | 24. | MILEWICH, et al. Metabolism of dehydroisoandrosterone and androstenedione in human pulmonary endothelial cells in culture. J Clin Endocrinol Metab. 1983; 56(5):930-5. | |
| | 25. | MILEWICH, et al. Testosterone metabolism by human lung tissue. J Steroid Biochem. 1978; 9(1):29-32. | |
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| | 27. | PONGRACZ, et al. Capillary gas chromatography of urinary steroids of terbutaline-treated asthmatic children. Chromatographia. 1998; 48(1/2): 163-165. | |
| | 28. | TYCZYNSKI, et al. Lung cancer in Europe in 2000: epidemiology, prevention, and early detection. Lancet Oncol. 2003; 4(1):45-55. | |

| UNPUBLISHED PATENT APPLICATIONS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | 29. | LEONARD, et al. US Patent Application No. 10/462,927, entitled "Dihydrate dehydroepiandrosterone and methods of treating asthma or chronic obstructive pulmonary disease using compositions thereof," filed June 17, 2003. (WSGR Reference No. 30775-722.201) | |

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